OBJECTIVES: To assess the cost-effectiveness of nutritional support (high protein supplementary diet) versus standard care (regular hospital diet) in preventing pressure ulcers in hospitalised patients at high risk of pressure ulcers and malnutrition. Further, to evaluate the need and value of additional research using value of information analysis. **METHODS:** Analyses were undertaken from the perspective of the State health department in Queensland, Australia, using a Markov decision model. Evidence for the relative risk (RR) was estimated from a meta-analysis of randomised controlled trials; other parameters were systematically identified from the literature to populate the model. The incremental net monetary benefit (INB) was calculated and a probabilistic sensitivity analysis using Monte Carlo simulation was conducted. The expected value of perfect information (EVPI), expected value of perfect parameter information (EVPPI), expected value of sample information (EVSI), expected total cost of additional research, expected net benefit of sampling (ENBS), and the return on investment (ROI) were calculated for an estimated population of 125,000 over ten years. **RESULTS:** At a willingness-to-pay of AU$ 50,000 per quality-adjusted life year, the INB was AU$ 530, with a probability of 84% for nutritional support to be the preferred intervention. The population EVPI was AU$ 4.75 million, the highest EVPPI was for RR at AU$ 2.25 million. For a future randomised study investigating the RR of the two interventions, the ENBS would be maximised at AU$ 380,000 with 1,200 patients in each arm; from an EVSI of AU$1.6 million and total study cost of AU$ 1.2 million. The expected ROI would be 32%. **CONCLUSIONS:** Nutritional support is cost-effective in preventing pressure ulcers in high risk hospitalised patients; however, there is uncertainty surrounding the decision and the value of this uncertainty is high. A future clinical trial to resolve this uncertainty is worthwhile.

PSS53

THE IMPACT OF THE GERMAN DRG-SYSTEM ON POLICY DECISION MAKING IN ENT

Fichtenbauer M, Kosaner M, Urban M
Vibrant Med-El Hearing Technology Gmbh, Innsbruck, Austria

OBJECTIVES: The German diagnosis-related groups (G-DRG) have been introduced as a reimbursement system for in-patient care. The aim of this study was to report on clinic-based data available from the G-DRG browser regarding the impact of middle ear implantation as a basis for future health care decision making in ear, nose and throat medicine (ENT). **METHODS:** Using a clinical algorithm, the unevaluated D23Z database from 2012 was analyzed to determine epidemiological characteristics of patients with different types of hearing losses and receiving middle ear implants (MEI). All ICD-10 Codes used for the diagnosis of conductive (CHL), mixed (MHL) or sensorineural hearing loss (SNHL) were extracted. The number of MEI cases reported in the D23Z was analyzed regarding Patient Clinical Complexity Level (PCCL), age, sex and duration of stay. The incidence of MEI candidates to the total number of ICD-10 codes and per indication were calculated. **RESULTS:** According to the D23Z, approximately 30`000 individuals admitted to ENT clinics were diagnosed with a hearing loss. About 38% suffered from CHL, 8% suffered from MHL and 48% suffered from SNHL. The proportion of patients who received a MEI per indication were respectively 0.8% for SNHL, 8% for MHL and 1% for CHL. Overall, about 466 (1%) patients received a MEI. 49.8% of them were men and 50.2% were women. Children aged as young as 1-2 years could also receive treatment. All patients had normal-term stay in hospitals with no comorbidities or complications (PCCL <4 in 99.2% of cases) The incidence of MEI to the ENT patient base and the German population were respectively 15.5/1,000 and 0.6/100,000. **CONCLUSIONS:** The overall number of middle ear implantations compared to standard treatments is quite low. Analyzing data on MEI available from highly-developed DRG systems can be used by other countries for policy decision making in ENT.

PSS54

UNDERSTANDING TRENDS IN OPHTHALMOLOGIST PATIENT SELECTION AND CARE BASED ON PATTERNS OF BILLING

Culp JL[1], Connelly N[1], Kristopik J[1], Doyle JJ[2]
[1]*Quintiles Consulting, Durham, NC, USA,* [2]*Quintiles, Hawthorne, NY, USA*

The recent U. S. release of Medicare Part B billing data provides unprecedented insight into a health care system that reimbursed $77 billion in 2012. Of the 100 physicians receiving the greatest payments, nearly half were ophthalmologists. **OBJECTIVES:** Examine ophthalmologist trends in patient selection and care, and implications on system value delivery, based on Medicare and other data. **METHODS:** We examined aggregate and line-item data, comparing the 100 highest billing ophthalmologists to each other, and to the remaining 16,971, identifying patterns in services billed, beneficiaries served, service location, and dollars billed, allowed and paid. We also compared volume and cost of a key office-based code (J2778: Ranibizumab injection) to a key facility-based code (67042: vitrectomy for macular hole), and incorporated epidemiology data to understand provider incentives and drivers of care. **RESULTS:** Ophthalmologists represented 2% of all practitioners billing Part B, but received 7% of reimbursement; the Top 100 billing ophthalmologists accounted for 0.6% of ophthalmologists billing, but received 8.8% of payments; disparities between Top 100 billers and non-Top 100 include: variety of patients treated, percent of charges reimbursed, and practice location; high volume J2778 performers were much more likely to be Top 100 billers than were high performers of 67042; and based on prevalence among those 65 and older, a significantly greater percentage of beneficiaries with wet AMD received treatment than did beneficiaries with macular hole. **CONCLUSIONS:** A large portion of payments were received by relatively few ophthalmologists, whose practices demonstrate disparities in variety and volume of procedures over non-top billers; incentives—some financial—may be factors that contribute to greater treatment of wet AMD than of macular hole; and a focus on conducting high-reimbursement services may drive disproportionate system costs. Greater transparency may drive changes in practitioner behavior, and reduce unnecessary health care system costs.

PSS55

FABRICATION OF VORICONAZOLE SOLID LIPID NANOPARTICLES FOR EFFECTIVE OCULAR DELIVERY

Kumar R, Sinha VR
UIPS, Panjab University, Chandigarh, India

OBJECTIVES: Preparation of Voriconazole (VCZ) solid lipid nanoparticles (SLNs) for effective ocular delivery for the treatment of fungal keratitis. **METHODS:** SLNs were prepared by solvent emulsification technique using Compritol (lipid), Pluronic F-68 (surfactant) and sodium taurocholate (co-surfactant). Characterization of SLNs was performed by size measurement, in-vitro release, ex-vivo corneal permeation studies and in-vitro antifungal activity. **RESULTS:** Particle sizes were found in the range of 150-300 depending upon lipid/S_{mix} ratio with good zeta potential. Entrapment efficiency of SLNs was found between 40-60% with sustained in vitro drug release (>70% in 12h). The ex-vivo corneal permeation studies exhibited good ocular permeation of VCZ from SLNs. Ex-vivo study also supports good ocular permeation of VCZ from SLNs when compared with drug suspension. Further, in-vitro antifungal activity exhibited the potential of VCZ SLNs. **CONCLUSIONS:** The sustained release property with good corneal permeation of VCZ from SLNs encourages its application for in-vivo studies and hence could be proposed as an effective carrier for ophthalmic administration.

PSS56

THE ANALYSIS OF DENTAL CARE IN UKRAINE AT THE REGIONAL LEVEL

Zaliskyy O, Shcherba P, Zalis'ka O
Danylo Halytsky Lviv National Medical University, Lviv, Ukraine

OBJECTIVES: The structure of the overall incidence diseases the mouth and teeth morbidity occupy the third place in Ukraine. Thus 99% of the patients served in outpatient clinics institutions. The structure of diseases requiring hospitalization (approximately 1% of patients), the top spot is occupied odontogenic inflammatory diseases and injuries of the maxillofacial face. **METHODS:** In Ukraine, the availability of dentists is 4.0 per 10 000 population and 4.5 per 10 000 children. We have analyzed the statistical data of the Lviv Regional Department of Health. We found that 98% of the population have dental problems. Prevalence of dental caries, temporary occlusion in 6-years children reached 87.9%, a 12-year-olds - 72.3%. Prevalence of chronic catarrhal gingivitis among adolescents aged 12-15 years ranged 70-98% and teeth abnormalities in children 7-18 years more than 80%. In Ukraine everyone requires a prosthetics after 50 years. **RESULTS:** Main social burden have the dental institutions of the state and municipal property. By 2013 there were about 1.5 million causes to the dental care. We determined that in Lviv region on the basis of licenses to practice medicine in dentistry are 248 dentists, who working in cities and towns, and only about 10% - in rural areas. From 196th private dental surgeries 89 are situated in the regional center. Danylo Halytsky Lviv National Medical University opened and acting university Dental Center from 2012, where dentists had treated about 400 000 people, including more than 172 000 children each year. Such preventive examinations make it possible to carry out monitoring as indicators of dental public health field, to identify the most important risk factors for dental diseases. **CONCLUSIONS:** The management and pharmacoeconomic studies of dental care, identifying optimal funding for state and municipal health care institutions for cost-effectiveness use of state funds.

PSS57

DENTAL CARE USE AND ASSOCIATED FACTORS AMONG PEOPLE WITH RHEUMATOID ARTHRITIS: A NATIONWIDE, POPULATION-BASED, PROPENSITY SCORE-MATCHED FOLLOW-UP STUDY

Chen YT
Yang-Ming University, Taiwan, Taiwan

OBJECTIVES: Patients with RA suffer from a higher risk of periodontal attachment loss and increased oral inflammation. There were few studies to access the utilization of dental care among RA in the Taiwan. The purpose is identify realize analyze and discuss the dental use of diabetic patients, and the association between the risk of rheumatoid arthritis (RA) and a history of periodontitis. **METHODS:** retrospective cohort studybased on the nationwide, population-based, NHIB used administrative data, case group consisted of 5,506 (age ≥18 years) patients with rheumatoid arthritis (RA group) as the study group and 22,024 patients without RA attending the Outpatient wing of Department of General Medicine formed the control group (NRA group). Matched for Age, gender and RUB, Both groups were matched on 1:4. **RESULTS:** More advanced forms of periodontitis were found in RA patients compared with controls. The results showed that RA patients (66.9% of RA) had 5-years utilization rate of dental care than non-RA patients (13.9% of non-RA). However, people have RA or not, the characteristics of dental use were similar. Only has the gender aspects to differ from, when the male suffered from RA, the utilization of dental care were not different with the female. **CONCLUSIONS:** we propose that the consulting rheumatologists inform the patients that they have a higher risk of periodontal. this study demonstrates an association between periodontitis and incident RA. And the study is limited to lack of BMI, smoking, alcohol status.

PSS58

MACULAR OEDEMA DUE TO RETINAL VEIN OCCLUSION METHODS FOR THE IDENTIFICATION OF TREATMENT GUIDELINES AND AREAS OF UNMET CLINICAL NEEDS BY MEANS OF SYSTEMATIC REVIEW

Patel AS
Abacus International, Bicester, UK

OBJECTIVES: Retinal vein occlusion (RVO) causes macular oedema (MO), which can lead to vision loss. The present study sought to identify treatment guidelines internationally by conducting a systematic review and extensive hand searches. The aims were to i) develop a systematic methodology for the identification of such guidelines ii) review the guidelines and treatment pathways identified in order to propose optimal positioning for an hypothetical intervention for the treatment of MO in RVO, and iii) to identify areas of unmet clinical needs. **METHODS:**

Systematic searches in the electronic databases MEDLINE, EMBASE and The Cochrane library were conducted and 53 online databases (including HTA agency websites, international ministries of health, and clinical trials. gov) were hand searched for clinical guidelines in the treatment of MO caused by RVO. **RESULTS:** Fifteen documents on treatment pathways or guidance used internationally were identified from the hand searches. No papers or abstracts were found from the electronic database searches. There were considerable between-jurisdiction differences in the guidance for the management of MO caused by RVO. These differences were consolidated to produce two amalgamated treatment pathways. In total, eight treatment positions for interventions in the treatment of RVO subtypes were identified. For one of the identified positions – treatment of ischaemic branch RVO – no licensed treatment currently exists. **CONCLUSIONS:** The described systematic methodology for the construction of treatment pathways may be used by manufacturers in early drug development decisions to identify unmet clinical needs, understand which treatment positioning may provide the most value, and identify future treatment comparators in the same indication. Guidelines to inform such commercial strategies may not be identifiable from electronic database searches alone with extensive hand searches being a necessity. Between jurisdiction guideline nuances also need to be taken into account when considering the target market for an intervention in development.

PSS59

OPHTHALMOLOGY: THERAPY TRENDS IN EUROPE BASED ON CLINICAL TRIAL REGISTRY DATA

Gupta A, Mukherjee B, Mahal SS, Mathews A
Novartis Healthcare Pvt Ltd, Hyderabad, India

OBJECTIVES: Ophthalmology pharmaceutical market is growing worldwide due to rising aging population, new delivery technologies and changing lifestyle. However, challenges like patent expiry of major brands and lack of awareness still persists. Therefore, it is important to be aware of the upcoming treatment options, changing patients' needs and requirement of cost effective therapies. This analysis provides an overview of the recent trends and future scenario in Ophthalmology market. **METHODS:** Pharmaceutical companies sponsored clinical trials initiated from January 2011 to April 2014 in Glaucoma, Age-related Macular Degeneration (AMD), Diabetic Retinopathy (DR) / Diabetic Macular Edema (DME), Dry eye syndrome (DES) and Retinal vein occlusion (RVO) have been considered. Only Phase I - III trials listed on public registries have been considered. **RESULTS:** The data showed that >30% of the trials are being conducted on Glaucoma in USA, Europe, Asia and Australia. This is followed by AMD (24%), DR/DME (21%), DES (17%) and RVO (7%). Also, >50% ophthalmological trials are being conducted in USA; followed by Europe (~25%) and Asia (~20%). In Europe, 71 trials have been conducted on 48 molecules, of which 69% are chemical entities, 19% are biologicals and >10% are entities like RNAi (oligonucleotide, aptamers), DARPin. Eye drops (46%) and intravitreal injections (37%) are the key topical and parenteral formulations, respectively. 10% of the trials have been conducted on oral formulations. In Europe, EU5 countries comprise of 43% of the trials and Germany has maximum 37 trials. Novartis has conducted trials in maximum 30 countries, followed by Santen (19), Pfizer (15) and Allergan (13) in Europe. **CONCLUSIONS:** Based on the analysis, currently, Glaucoma, AMD and DR/DME are the major focus of the companies in ophthalmology. Though, biologicals and RNAi are being tested routinely, chemical entities are foremost modalities. Similarly, eye drops remain as preferred method of delivery with respect to other newer delivery techniques.

RESEARCH POSTER PRESENTATIONS - SESSION V

DISEASE-SPECIFIC STUDIES
CANCER – Clinical Outcomes Studies

PCN1

TREATMENT PATTERNS AND HEALTH OUTCOMES AMONG PATIENTS WITH RADIOIODINE-REFRACTORY DIFFERENTIATED THYROID CANCER IN THE UNITED STATES AND WESTERN EUROPE

Gianoukakis AG[1], Flores NM[2], Pelletier CL[3], DiBonaventura M[2], Forsythe A[3], Wolfe G[2], Rege J[3], Taylor MH[4]
[1]*University of California, Los Angeles, Torrance, CA, USA,* [2]*Kantar Health, New York, NY, USA,* [3]*Eisai Inc, Woodcliff Lake, NJ, USA,* [4]*Oregon Health & Science University, Division of Hematology & Medical Oncology, Portland, OR, USA*

OBJECTIVES: Most patients with differentiated thyroid cancer (DTC) have an excellent prognosis after receiving standard treatment, consisting of surgery and often adjuvant radioactive iodine (RAI). However, a subgroup of patients prove to have progressive DTC which is refractory to RAI (RRDTC). Treatment options for RRDTC are limited. This study investigated the treatment patterns and health care resource utilization of patients with RRDTC. **METHODS:** Data were collected by performing a retrospective chart review study in the US and 5EU (France, Germany, Italy, Spain, UK) with physicians recruited from an online panel. Physicians provided clinical information on 1 to 4 of their RRDTC patients in an online survey. Demographics, disease history, treatment information, and health care resource were included and reported descriptively. Health care resource use was compared across treatment classes using general linear models. **RESULTS:** 231 physicians participated and provided a total of 700 patient charts (44.1% of charts were from the US and 11-12% from each 5EU country). 45.0% of patients were male with a mean age at diagnosis of 55.1 years [SD=12.4]. 52.0% of patients were treated with systemic treatment (e.g., 16.9% tyrosine kinase inhibitors [TKIs] only; 13.3% chemotherapy only). The remaining 48.0% were either in a watch and wait ("WW") period (20.1%) or were managed with non-systemic palliative therapies (27.9%; eg, external beam radiation). Overall, patients averaged 15.87 days hospitalized per year (due to disease related complications or side effects). Although not statistically significant (p>.05), a trend toward more days hospitalized from disease-associated complications was observed for patients managed with WW (Mean=9.21, respectively) and non-systemic treatment (Mean=8.27) than patients treated with chemotherapy (Mean=7.25) or TKIs (Mean=8.22). **CONCLUSIONS:** Among patients diagnosed with RRDTC, watch and wait and non-systemic treatment options remain common. A large direct cost burden may be observed given the frequent and long hospital stays.

PCN2

APPROVING DRUGS BASED ON EARLY STAGE DATA - HOW PHASE II TRIAL DATA CORRELATES WITH PHASE III OUTCOMES. CASE STUDY: NSCLC

Macaulay R, Tan H
HERON Commercialization, London, UK

OBJECTIVES: There is increasing pressure on regulators from patients, physicians and industry for earlier access to pharmaceuticals for serious diseases. In reaction, in March 2014 the European Medicines Agency (EMA) announced it was piloting adaptive licensing, and the Medicines and Health care products Regulatory Agency (MHRA) unveiled their Early Access to Medicines Scheme. Nevertheless, there are questions over how, and if, Phase II trial benefits can be predictive of clinical advantages in Phase III studies, which this research aims to address. **METHODS:** Phase III data of any Non-Small Cell Lung Cancer (NSCLC) oncologic appraised by the EMA, or that had failed Phase III clinical trials, since 2002 was extracted along with its corresponding Phase II data. Statistical tests were conducted using Pearson's coefficient correlation. **RESULTS:** 12 oncologics were identified with both Phase II and III readouts, 6 of which met their Phase III trial primary endpoint. Overall Response Rates (ORRs) reported in Phase II trials varied from 0%-61% (mean 24%). 4/4 (100%) drugs with Phase II ORRs >30% met their primary endpoint vs. only 2/8 (25%) with ORRs ≤30%. Phase II ORRs were strongly correlated with Phase III Progression-Free Survival (PFS) (r^2=0.864, p<0.0005) and Overall Survival (OS) outcomes (r^2=0.858, p<0.001). Nevertheless, 5/6 drugs that failed their Phase III primary endpoints had comparative Phase II data indicating benefits versus these same comparators, most notably onartuzumab, whose Phase III trial was terminated early due to lack of efficacy, despite demonstrating significant OS benefits of 8.8 months in Phase II. **CONCLUSIONS:** In NSCLC, Phase II ORRs can be strongly predictive of the magnitude of PFS and OS readouts in Phase III trials. However, comparative advantages in Phase II trials seem to be poorly predictive of OS benefits in Phase III studies, raising questions over the appropriateness of approving drugs on early stage comparative data.

PCN4

CERVICAL HUMAN PAPILLOMA VIRUS (HPV) DNA PRIMARY SCREENING TEST RESULTS OF THE EXPERIENCE OF A REGIONAL LABORATORY IN CENTRAL ITALY

Passamonti BU[1], Bulletti S[1], Gustinucci D[1], Martinelli N[1], D'Amico MR[1], Spita N[1], Malaspina M[1], Carlani A[1], DI Dato E[1], Galeazzi P[1], Tintori B[1], D'angelo V[1], Calvi C[2]
[1]*Centro Unico di Screening Regione Umbria, PERUGIA, Italy,* [2]*ROCHE DIAGNOSTICS, MONZA, Italy*

OBJECTIVES: To investigate feasibility and effectiveness of a cervical screening program with DNA tests as preliminary assay versus usual cytology protocols in Umbria Region. **METHODS:** A large cohort of 35-64 aged women afferent to the unique regional laboratory was considered. The usual algorithm with cervical cytology as primary test was followed in January 2008–June 2010, whereas in August 2010–October 2011 high-risk human papillomavirus (HR-HPV) DNA test was used as primary screening. The cohorts were compared in terms of acceptance rate of invitation, cytological results, molecular results including HPV genotype, detection rate of histological lesions. **RESULTS:** A total of 31,228 women were invited: 21,249 were suggested to undergo classical cervical cytology screening, 9,979 HR-HPV DNA test as primary screening. A similar rate of adhesion (56.6% vs. 56.5%) was observed. Age-related differences were evidenced, with younger women (35-49) more prone to accept the invitation to HR-HPV DNA testing rather than usual cytology screening (61.6% vs. 55.5%; p<0.0001); analogously, uninvited younger women spontaneously requesting cervical screening were more prone to specifically request molecular than classical cytological testing (24.8% vs. 10.8%; p<0.0001). Among the 6,272 HR-HPV DNA testing women, 396 (6.4%) were positive, and, among them, 141 (36%) featured an altered cytology. All patients with altered cytology were suggested to undergo colposcopy and 106 out of 141 (75.1%) answered to the invitation. Among them, 89 (84%) featured abnormal histology with 48 (45.3%) CIN1 and 41 (38.7%) CIN2. If comparing the CIN2 detection rate within the two studied periods, it was almost doubled using the HR-HPV DNA than pap test as primary assay (0.64% vs. 0.37%; p=0.005). Finally, the implementation of the DNA test screening program did not increase total costs. **CONCLUSIONS:** Although with some limits, the introduction of HR-HPV DNA primary testing resulted feasible and effective, significantly increasing detection of severe lesions.

PCN5

COMPARATIVE EFFECTIVENESS OF TREATMENTS FOR RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA (R/R MCL), USING MATCHING ADJUSTED INDIRECT COMPARISON

Tongbram V[1], Sengupta N[2], Gaudig M[3], Sidhu M[1], Exuzides A[4], Colby C[4], Sanden SV[5], McGovern A[1]
[1]*ICON Plc, Morristown, NJ, USA,* [2]*Janssen Pharmaceuticals, Inc, Raritan, NJ, USA,* [3]*Janssen Pharmaceuticals, Inc, Neuss, Germany,* [4]*ICON Plc, San Francisco, CA, USA,* [5]*Janssen Pharmaceuticals, Inc., Beerse, Belgium*

OBJECTIVES: Prognosis for relapsed or refractory (R/R) MCL patients with existing treatments is poor; most patients progress within ~4 months. Ibrutinib, an oral once daily Bruton's tyrosine kinase inhibitor showed durable single agent activity with good response rate in 111 R/R MCL patients and a median progression free survival (PFS) of 13.9 months. Ibrutinib received breakthrough designation and United States Food and Drugs Administration approval for use in MCL patients who received at least one prior therapy (R/R MCL). This indirect analysis aims to compare the efficacy